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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,491	10/01/2003	Jean-Pascal Hirt	235016US26	4669

22850 7590 06/01/2009

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EXAMINER	
FOREMAN, JONATHAN M	

ART UNIT	PAPER NUMBER
3736	

NOTIFICATION DATE	DELIVERY MODE
06/01/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/674,491	HIRT ET AL.	
	Examiner	Art Unit	
	JONATHAN ML FOREMAN	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-25,30,32-56,71,73-79 and 84-87* is/are pending in the application.

4a) Of the above claim(s) *14-16,21,23-25,46-48,53,55 and 56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-13,17-20,22,30,32-45,49-52,54,71,73-79 and 84-87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/27/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 2/27/09 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 35 and 87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 87 recites the broad recitation 10 – 2% by weight, and the claim also recites 10 – 6% by weight which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 4 – 6, 13, 17 – 20, 22, 30, 32, 36 – 38, 45, 49 – 52, 54, 71, 73, 74, 76, 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. in view of Pepe et al. and in view of U.S. Patent No. 6,358,231 to Schindler et al.

In regard to claims 1, 4 – 6, 13, 17 – 20, 22, 30 – 32, 36 – 38, 45, 49 – 52, 54, 71, 73, 74, 76, , Zhang et al. disclose a plurality of applicators capable of containing different test substances (Col. 5, lines 20 – 25) each applicator comprising: a tube (40); a plug inside the tube (58); and at least one test substance (48) contained in an inside space of the tube defined at a first end by the plug, the plug being arranged, in use, to be expelled together with the test substance when said test substance leaves the inside space of the tube (Figure 3). Zhang et al. disclose a tube, wherein the inside space is defined at a second end (46), remote from the first, by a breakable portion (42). Zhang et al. disclose the applicator includes a retaining element for retaining the breakable portion on the applicator after it has been broken off (Figure 3, 42). Zhang et al. disclose the tube (40) being provided at one end with an applicator element (72), the applicator element being separated from the test substance prior to use, by the plug (Figure 2, 58). Zhang et al. disclose a kit, wherein the applicator element (72) is selected from the group consisting of a cotton bud (Column 5, line 62 – Column 6, lines 3), a foam bud, a felt tip, a flocked bud, and a tip made of ceramic or of sintered material. Zhang et al. disclose the tube is free of an applicator element (Figure 1). Zhang et al.

disclose the plug comprises a liquid, and wherein said liquid is selected from the group consisting of mineral oils, fluorine-containing substances, and silicones (Column 5, lines 44 – 47). Zhang et al. disclose at least three applicators having different test substances (Col. 5, lines 20 – 25). However, Zhang et al. fails to disclose the housing having at least three applicators, a first applicator including a first tube containing a first test substance comprising a compound at a first concentration, a second applicator including a second tube containing a second test substance comprising said compound at a second concentration, and a third applicator including a third tube containing a third test substance comprising said compound at a third concentration, wherein the at least one compound varies by a factor of at least two from one applicator to another. Pepe et al. disclose the use of three test substances comprising a stimulating agent for stimulating a peripheral nervous system including a compound at a first, second and third concentrations wherein the compound varies by a factor of at least two from one substance to another (See Abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the kit disclosed by Zhang et al. to include at least three substances with at least one compound at concentrations varying by a factor of at least two from one to another as taught by Pepe et al. in order to perform an evaluation of topical tretinoin on skin micro-roughness. Zhang et al. in view of Pepe et al. fail disclose packaging in which the applicators are housed. Schindler et al. discloses a kit having a plurality of applicators housed in a housing, wherein the housing includes at least one compartment configured to receive a single applicator or a plurality of applicators (Figure 7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the kit as disclosed by Zhang et al. in view of Pepe et al. to include a packaging having compartments as taught by Schindler et al. in order to keep the applicators sterile and from moving around during transport.

6. Claims 7, 8, 39, 40 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. in view of Pepe et al. and U.S. Patent No. 6,358,231 to Schindler et al. as applied to above, and further in view of Zygmont (US Patent No. 6,488,646).

In regard to claims 7, 39 and 77, Zhang et al. in view of Pepe et al. and Schindler et al. disclose a packaging for at least one applicator. However, Zhang et al. in view of Pepe et al. and Schindler et al. do not disclose at least one bag for packaging at least one applicator. Zygmont discloses one bag (2) for packaging at least one applicator (Figure 1). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Zygmont to enclose a bag around an applicator with Zhang et al. in view of Pepe et al. in view of Schindler et al. in order to keep each applicator sterile.

In regard to claims 8 and 40, Zhang et al. in view of Pepe et al. and Schindler et al. and further in view of Zygmont disclose the claimed invention except for a string of bags each containing at least one applicator. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a string of bags for each of the applicators, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

7. Claims 9, 10, 41 and 42, are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. in view of Pepe et al. and U.S. Patent No. 6,358,231 to Schindler et al. as applied above, and further in view of Barabino et al. (US Patent No. 4,740,194).

In regard to claims 9, 10, 41 and 42, Zhang et al. in view of Pepe et al. and Schindler et al. disclose an applicator that is labeled (Column 2, lines 57-58). However, Zhang et al. in view of Pepe et al. and Schindler et al. do not disclose each applicator includes at least one mark corresponding to

at least one of a type of test substance inside the tube and a concentration of a compound contained in the test substance. However, Barabino et al. discloses each applicator includes at least one mark comprising one of an alphanumeric symbol and a color corresponding to at least one of a type of test substance inside the tube and a concentration of a compound contained in the test substance (Column 6, lines 6-8). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Barabino et al. to include a marking on each applicator with Zhang et al. in view of Pepe et al. and Schindler et al. in order to differentiate applicators and their respective content.

8. Claims 11, 12, 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. in view of U.S. Patent No. 6,358,231 to Schindler et al. as applied above, and further in view of Tobin et al. (US Patent No. 3,792,699).

In regard to claims 11, 12, 43 and 44, Zhang et al. in view of Pepe et al. and Schindler et al. fail to disclose the substance in each tube having a volume in a range from 0.01 ml to 5 ml or 0.05 ml to 1 ml. Tobin et al., however, discloses a kit, wherein the tube has a volume in the range of 0.01 ml to 5 ml or 0.05 ml to 1 ml (Column 3, lines 20-25). It would have been obvious to one having ordinary skill in the art at the time the invention was made in view of Tobin et al. to modify the volume of the tubes as disclosed by Zhang et al. in view of Pepe et al. and Schindler et al. to be the range from 0.01 ml to 5 ml or 0.05 ml to 1 ml in order to sufficiently moisten the applicator region.

9. Claims 1, 30, 32 – 35 and 84 – 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. in view of Barr et al. (US Patent No. 6,812,254) and further in view of U.S. Patent No. 6,358,231 to Schindler et al.

In regard to claims 1, 30, 32 – 35 and 84 – 87, Zhang et al. in view and Schindler et al. disclose a plurality of applicators containing different test substances (Col. 5, lines 20 – 25) each applicator comprising: a tube (40); a plug inside the tube (58); and at least one test substance (48) contained in an inside space of the tube defined at a first end by the plug, the plug being arranged, in use, to be expelled together with the test substance when said test substance leaves the inside space of the tube (Figure 3). Zhang et al. in view of Schindler disclose a kit capable of comprising pharmaceutical products (Abstract). Zhang et al. disclose at least three applicators having different test substances (Col. 5, lines 20 – 25). However, Zhang et al. fails to disclose the housing having at least three applicators, a first applicator including a first tube containing a first test substance comprising a compound at a first concentration, a second applicator including a second tube containing a second test substance comprising said compound at a second concentration, and a third applicator including a third tube containing a third test substance comprising said compound at a third concentration, wherein the at least one compound varies by a factor of at least two from one applicator to another. Barr et al. discloses a kit comprising at least three test substances with a substance capable of being at varying concentrations by at least two(Column 3, lines 44-65 & Column 7, line 40 – Column 8, line 38). The substances include a stimulating agent for stimulating a peripheral nervous system (Abstract & Column 4, lines 5-23).). The stimulating agent for stimulating the peripheral nervous system is selected from the group consisting of natural or synthetic capsaicinoids, homocapsaicin, homodihydrocapsaicin, nordihydrocapsaicin, dihydrocapsaicin; lactic acid, glycolic acid, ethanol at a concentration greater than 50%, mustard seed oil (Barr et al., Column 3, lines 14-18). A concentration of the stimulating agent for stimulating the peripheral nervous system lies in a range from 10-6% to 10-2% by weight (Barr et al., Column 3, lines 45-65). It would have been obvious to one having ordinary skill in the art at the time the

invention in view of Barr et al. to have different test substances with varying concentrations with Zhang et al. in view of Schindler et al. in order to administer varying levels of treatment for pains and discomforts (Column 1, lines 6 – 12). Zhang et al. in view of Barr et al. fail disclose packaging in which the applicators are housed. Schindler et al. discloses a kit having a plurality of applicators housed in a housing, wherein the housing includes at least one compartment configured to receive a single applicator or a plurality of applicators (Figure 7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the kit as disclosed by Zhang et al. in view of Barr et al. to include a packaging having compartments as taught by Schindler et al. in order to keep the applicators sterile and from moving around during transport.

10. Claim 75 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. in view of Pepe et al. and U.S. Patent No. 6,358,231 to Schindler et al. as applied above, and further in view of Lewis and further in view of Ohsumi (US Patent No. 5,658,981).

In regard to claim 75, Zhang et al. in view of Pepe et al. and Schindler et al. fail to disclose each tube further comprises a thermoreversible thickener inside the volume. Ohsumi, however, teaches the use of thermoreversible thickener (Abstract & Column 1, lines 43-52). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Ohsumi to add thermoreversible thickener to the volume with Zhang et al. in view of Pepe et al. and Schindler et al. in order to control aqueous solutions, which thicken rapidly within a narrow temperature range (Column 1, lines 43-52).

11. Claims 78 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. in view of Pepe et al. and U.S. Patent No. 6,358,231 to Schindler et al. as applied above, and further in view of Lewis (US Patent No. 5,947,986).

In regard to claims 78 and 79, Zhang et al. in view of Pepe et al. and Schindler et al. disclose a packaging, but fail to disclose the packaging having a stand; a body mounted on the stand and a closure cap coupled to the body of the portions of tubes extending outside the body. However, Lewis discloses a packaging including a stand (Lewis, 52); and a body (Lewis, 56) mounted on said stand. Each tube in the packaging (Lewis, 12) has a portion extending outside said body (Lewis, 56), and a closure cap (Lewis, 60) coupled to said body and over said portions. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the packaging as disclosed by Zhang et al. in view of Pepe et al. and Schindler et al. to include a body, stand and cap as taught by Lewis in order to make the tubes more easily accessed by the user.

Response to Arguments

12. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN ML FOREMAN whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. F./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736